

AUG 1 8 2000

K002209

### 510(k) Summary of Safety and Effectiveness

**Date:** July 21, 2000

**Submitter:** GE Marquette Medical Systems, Inc.  
8200 W. Tower Ave.  
Milwaukee, WI 53223 USA

**Contact Person:** Kristin Pabst  
Corporate Regulatory Affairs  
GE Marquette Medical Systems  
Phone: (414) 362-2793  
Fax: (414) 371-3736

**Trade/Proprietary Name:** GE Marquette ECG Analysis Program

**Common/Usual Name:** ECG Analysis Program

**Classification Names & Citations:**

21 CFR 870.1425 Programmable diagnostic computer	74DQK
21 CFR 870.2920 Transmitters and Receivers, Electrocardiograph, Telephone	74DXH
21 CFR 870.2340 Electrocardiograph	74DPS
21 CFR 870.2340 System, ECG Analysis	74LOS
21 CFR 870.1025 Detector and Alarm, Arrhythmia	74DSI

**Predicate Device:** MAC 5000 resting ECG analysis system K991735

**Device Description:** GE Marquette ECG Analysis Program is a software algorithm that runs on GE Marquette's electrocardiographs.

**Intended Use:** The GE Marquette ECG Analysis Program assists the physician in interpreting resting 12-lead ECGs for rhythm and contour information by providing an initial automated interpretation. Interpretation by the product is then confirmed, edited, or deleted by the physician. The product is intended for use in the general population ranging from healthy subjects to patients with cardiac and/or non-cardiac abnormalities. The product is intended for use in hospitals, outpatient clinics, emergency departments, and out-of-hospital sites such as ambulances and patients' homes.

**Technology:** The GE Marquette ECG Analysis Program employs the same functional technology as the predicate device.

**Test Summary:** The GE Marquette ECG Analysis Program and its host electrocardiograph complies with the voluntary standards as detailed in Section 9 of this submission.

The following quality assurance measures were applied to the development of the GE Marquette ECG Analysis Program

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Code inspections
- Verification and Validation

**Conclusion:** This premarket notification submission demonstrates that the GE Marquette ECG Analysis Program is substantially equivalent to the 12SL ECG analysis program cleared with the MAC 5000 resting ECG analysis system. These devices have the same intended use and the changes made do not raise new questions of safety or effectiveness.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

AUG 18 2000

Laura L. McComis  
Corporate Regulatory Affairs  
GE Marquette Medical Systems  
8200 W. Tower Avenue  
Milwaukee, WI 53223

Re: K002209  
GE Marquette ECG Analysis Program  
Regulatory Class: III (three)  
Product Code: 74 MHX  
Dated: July 21, 2000  
Received: July 21, 2000

Dear Ms. McComis:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the

Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4346. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

*for Mark N. Milburn*

James E. Dillard III  
Director  
Division of Cardiovascular  
and Respiratory Devices  
Office of Device Evaluation  
Center for Device  
and Radiological Health

Enclosure

510(k) Number (if known):                      Unknown;                      510(k) filed on July 13, 2000

**Device Name:**                      **GE Marquette ECG Analysis Program**

Indications For Use:

The GE Marquette ECG Analysis Program assists the physician in interpreting resting 12-lead ECGs for rhythm and contour information by providing an initial automated interpretation. Interpretation by the product is then confirmed, edited, or deleted by the physician. The product is intended for use in the general population ranging from healthy subjects to patients with cardiac and/or non-cardiac abnormalities. The product is intended for use in hospitals, outpatient clinics, emergency departments, and out-of-hospital sites such as ambulances and patients' homes.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use\_\_\_\_\_  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use\_\_\_\_\_

(Optional Format 1-2-96)

  
Division of Cardiovascular & Respiratory Devices  
510(k) Number                     K 002209